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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,484

06/29/2005

Wei Zhang

2565/130

6518

26646

7590

09/29/2006

KENYON & KENYON LLP  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/520,484

Applicant(s)

ZHANG, WEI

Examiner

Phil Wiest

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/6/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 102304130, filed on July 7, 2002.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17, 19-26, and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Spickermann (US 6,736,789).

With respect to Claim 24, Spickermann discloses an extracorporeal blood treatment device comprising a blood treatment apparatus 15, an arterial branch of the blood line 5 and a venous branch of the blood line 7. The blood circuit includes means for generating and measuring pulse waves that have a propagation rate and transfer time (Column 2, Lines 55-61). Spickermann further discloses a computer unit which calculates the blood pressure from the pulse wave transit time (Column 3, Lines 21-26). Once blood pressure and transit time are recorded from the sensors, blood volume can be calculated by the computer (Column 5, Lines 26-37 and 54-61).

With Respect to Claim 15, Spickermann discloses a method for the calculation of blood volume comprising a blood treatment apparatus 15, an arterial branch of the blood line 5 and a venous branch of the blood line 7. The blood circuit includes means for generating and measuring pulse waves that have a propagation rate and transfer time (Column 2, Lines 55-61). Spickermann further discloses a computer unit which calculates the blood pressure from the pulse wave transit time (Column 3, Lines 21-26). Once blood pressure and transit time are recorded from the sensors, blood volume can be calculated by the computer (Column 5, Lines 26-37 and 54-61).

With respect to Claims 25, 26, and 28 Spickermann discloses that a blood pump 6 and pressure sensor 46 are arranged in the extracorporeal blood circuit. Regarding Claim 25, it is well known in the art that the use of a blood pump will generate pulse waves. Furthermore, regarding Claim 28, Spickermann discloses that a pressure sensor 46 is arranged in the arterial branch of the blood line 5. See Figure 1.

With respect to Claims 16, 17, 19, Spickermann discloses a method for the determination of blood volume wherein a blood pump 6 and pressure sensor 46 are arranged in the extracorporeal blood circuit. Regarding Claim 16, it is well known in the art that the use of a blood pump in a blood circuit will generate pulse waves. Furthermore, regarding Claim 19, Spickermann discloses that a pressure sensor 46 is arranged in the arterial branch of the blood line 5. See Figure 1.

With respect to Claims 29-32, Spickermann discloses that the blood circuit comprising a computer that calculates blood pressure from the pulse wave transit time (Column 3, Lines 21-26). Furthermore, the computer is capable of calculating the

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relative blood volume using blood pressure and temporal change in the measured transit time (Column 5, Lines 26-37). The “continuous, noninvasive measurement of blood pressure” allows volume calculations to be made at any set of times  $t$  and  $t_0$  (Column 5, Lines 15-16). Regarding the relative blood volume equation of Claims 31 and 32, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner’s position that since the structural features of the device are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

With respect to Claims 20-23, Spickermann discloses a method for the determination of a blood volume comprising the use of a computer that calculates blood pressure from the pulse wave transit time (Column 3, Lines 21-26). Furthermore, regarding Claims 22 and 23, the computer is capable of calculating the relative blood volume using blood pressure and temporal change in the measured transit time (Column 5, Lines 26-37). The “continuous, noninvasive measurement of blood pressure” allows volume calculations to be made at any set of times  $t$  and  $t_0$  (Column 5, Lines 15-16). Regarding the relative blood volume equation of Claims 22 and 23, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data

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of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner's position that since the steps of the method are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spickermann in view of Pedrazzi (US 6,966,979). Spickermann discloses that a pressure sensor 46 is located in the arterial branch 5 of the blood line. Spickermann, however, does not disclose that a second sensor is located in the venous branch 7 of the blood line. Pedrazzi discloses an extracorporeal blood circuit comprising a sensor 32 in the arterial line 12 and a sensor 33 that is positioned on the venous line 15, downstream from the treatment apparatus 4 (Column 4, Lines 22-37). One of ordinary skill in the art would have been motivated to modify the extracorporeal blood circuit of Spickermann with the pressure in the venous line of Pedrazzi, since doing so would allow for the calculation of the blood volume being returned to the body.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spickermann in view of Pedrazzi (US 6,966,979). Spickermann discloses a method for

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determining blood volume wherein a pressure sensor 46 is located in the arterial branch 5 of the blood line. Spickermann, however, does not disclose that a second sensor is located in the venous branch 7 of the blood line. Pedrazzi discloses an extracorporeal blood circuit comprising a sensor 32 in the arterial line 12 and a sensor 33 that is positioned on the venous line 15, downstream from the treatment apparatus 4 (Column 4, Lines 22-37). One of ordinary skill in the art would have been motivated to modify the extracorporeal blood circuit of Spickermann with the pressure in the venous line of Pedrazzi, since doing so would allow for the calculation of the blood volume being returned to the body.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zhang (US 6527728) discloses a process and device capable of determining blood volume in an extracorporeal blood circuit (Column 3, Lines 56-61).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
9/21/2006

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.